UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Robert Freedman, on behalf of himself and all others similarly situated,

Plaintiff,

v.

Civil No. 12-3070 (JNE/JJG)
ORDER

Saint Jude Medical, Inc., Daniel J. Starks, John C. Heinmiller, Eric S. Fain, Michael T. Rousseau, and Donald J. Zurbay,

Defendants.

Gregg Levin and Joshua Littlejohn, Motley Rice LLC, Joshua D'Ancona, Kessler Topaz Meltzer & Check LLP, and James Anderson, Heins Mills & Olson PLC, appeared for the Lead Plaintiff.

Daniel Ring and Laura Hammargren, Mayer Brown LLP, appeared for the Defendants.

This is a private securities fraud case and a putative class action against St. Jude Medical, Inc. and five of its officers. It began as two separate actions that were both filed in this District in December 2012. Those cases were consolidated under the *Freedman* caption in March 2013 and the Institutional Investor Group was appointed as the Lead Plaintiff. Order, ECF No. 38. Thereafter, the Lead Plaintiff filed an Amended Consolidated Complaint ("ACC"). ECF No. 48. The ACC alleges that the Defendants committed fraud on the market from February 5, 2010 to November 20, 2012 and seeks relief for those who purchased stock during that class period.

The case is now before the Court on the Defendants' Motion to Dismiss the ACC for failure to meet the pleading requirements of the Private Securities Litigation Reform Act of 1995. ECF No. 63. *See* 15 U.S.C. § 78u-4(b)(3)(A). For the reasons discussed below, the motion will be granted in part and denied in part.

Background

As the matter is before the Court on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the factual context that follows is drawn from the allegations in the ACC and the documents it incorporates by reference. *See In re K-tel Int'l., Inc. Sec. Litig.*, 300 F.3d 881, 889 (8th Cir. 2002) ("The court may consider, in addition to the pleadings, materials 'embraced by the pleadings' and materials that are part of the public record.").

I. Defendants.

Saint Jude Medical (hereinafter, "SJM") is a corporation based in Minnesota that develops, manufactures, and distributes medical devices worldwide. At all times relevant to this case, Daniel Starks served as SJM's Chairman, President, and Chief Executive Officer, and Michael Rousseau served as Group President.

The other individual defendants' positions were affected by a restructuring that took place in August 2012 in which SJM reorganized its operations from four divisions down to two. Donald Zurbay, who had served as Corporate Controller before the realignment, became Vice President for Finance and Chief Financial Officer, while John Heinmiller, who had previously served as Executive Vice President and CFO, retained the former title. Also, Eric Fain, who had been President of SJM's Cardiac Rhythm Management Division ("CRMD") before realignment, became President of the newly-created Implantable Electronic Systems Division ("IESD") afterwards.

II. Regulatory controls.

At the core of the claims the Lead Plaintiff asserts against SJM and these five officers are the safety and reliability of two generations of leads developed and manufactured by the company's CRMD and IESD. Leads are custom-designed, insulated wires that connect implanted devices like a pacemaker or an implantable cardioverter defibrillator ("ICD") to the patient's heart, transmitting information about the beating of the heart to the device and, in turn, delivering therapeutic electrical impulses from the device to the heart. Because defibrillation and pacing leads thus provide "life-supporting or life-sustaining" therapy, the Food and Drug Administration categorizes them as Class III medical devices. 21 C.F.R. § 860.93. As such, these leads are subject to the most stringent regulatory controls, including premarket approval and post-market surveillance. *See id.* § 860.3(c)(2).

Among the controls that apply to all medical device manufacturers are the FDA's Quality System regulations. *See id.* Pt. 820. These provisions, which incorporate Current Good Manufacturing Practices ("CGMP"), require medical device manufacturers to utilize processes and procedures that will ensure the safety and effectiveness of their products. *Id.* § 820.1(a). Rather than "prescribe in detail how a manufacturer must produce a specific device," however, the regulations describe the essential elements of a quality system – such as verification and validation of a device's design with objective evidence, as well as maintenance of a "design history file" documenting the device's development – and provide the framework within which the manufacturer must "develop and implement specific procedures tailored to their particular processes or devices." 61 Fed. Reg. 52,602, 52,603 (Oct. 7, 1996). The FDA conducts inspections of manufacturers' procedures, facilities, and records to ensure compliance.

As one particular component of a quality system, manufacturers are required to have procedures in place for handling complaints, which includes conducting an investigation whenever information suggests that a device may have failed to meet any of its specifications. 21 C.F.R. § 820.198. Relatedly, leads are also covered by the FDA's Medical Device Reporting ("MDR") program, which is a mechanism for detecting and tracking problems with regulated products in the field. *See* 21 C.F.R. Pt. 803. Under MDR regulations, "device user facilities" – essentially, hospitals and other health care centers – are required to report to both the FDA and the manufacturer whenever a lead is believed to have caused or contributed to a patient's death. *Id.* § 803.30(1)(1). User facilities are also required to report to the manufacturer when a serious injury occurs that may reasonably be attributed to a lead. *Id.* § 803.30(a)(2).

In turn, when the manufacturer receives information about an adverse event involving its lead – whether from a user facility or through a complaint from any other source – it is required to conduct its own investigation and report to the FDA if the incident involved either (1) a death or serious injury to a patient attributable to the lead or (2) a malfunction of the lead that could cause a death or serious injury if it were to recur in the same or a similar product. *Id.* § 830.50. The adverse event reports that are sent to the FDA are compiled in the agency's Manufacturer and User Facility Device Experience ("MAUDE") database, which is publicly accessible online. *See* U.S. Food and Drug Administration, *MAUDE – Manufacturer and User Facility Device Experience*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last updated Jan. 31, 2014).

III. SJM's leads.

As for the two generations of SJM leads that are at issue here, the older of the two is characterized by the all-silicone insulation that houses the lead wires. SJM produced two series of defibrillation leads with this type of silicone rubber insulation: the Riata models, which were first approved by the FDA in 2001, and the Riata ST models, which were approved in 2006. SJM also produced a family of silicone-insulated pacing leads, marketed as the QuickSite and QuickFlex.

In contrast, the insulation in the newer generation of SJM leads is a proprietary blend of silicone and polyurethane known by the trade name Optim. SJM's series of Optim-insulated defibrillator leads was first approved by the FDA in 2006 as the Riata ST Optim; the name was changed in 2008 to the Durata. SJM also introduced Optim-insulated pacing leads, called the QuickFlex µ and Quartet.

IV. FDA attention in 2009-10.

All of these leads were developed and manufactured at the SJM facility in Sylmar, California, headquarters for the company's CRMD and, after realignment, the IESD. This facility was inspected by the FDA in June and July of 2009. At the conclusion of the inspection, the FDA's Lead Inspector issued a Form 483, which is a report prepared in the field that documents the inspectors' observations of objectionable conditions at a facility. While the issuance of a Form 483 does not constitute a final agency determination that the facility is in violation of the Food, Drug, and Cosmetic Act or its regulations, it is intended to prompt the management of the facility to take corrective action to obviate the need for the FDA to resort to

more formal enforcement actions, the next step towards which would be the issuance of a Warning Letter.

In this particular Form 483, the FDA inspectors noted deficiencies in SJM's quality system at Sylmar, particularly its documentation of and procedures for validating, verifying, reviewing, and approving design changes in its CRMD products, including Riata and Durata leads. The inspectors also focused on SJM's handling of complaints and adverse event reports, noting shortcomings in SJM's review and investigation of incidents of death or injury involving patients implanted with Riata and Durata leads as well as with the timeliness, completeness, and accuracy of the information it submitted to the FDA.

The following year, in May and June of 2010, the FDA inspected SJM's manufacturing facility in Arecibo, Puerto Rico, which produces leads and other devices. This inspection also resulted in the issuance of a Form 483, which identified deficiencies in SJM's MDR reporting and quality control procedures at that facility.

V. Failures of silicone-insulated leads.

By 2010, along with these criticisms of its quality system from the FDA, the Lead Plaintiff alleges that SJM was aware that serious flaws with its silicone-insulated leads had manifested in the field. One of these flaws was a susceptibility to premature inside-out abrasion, in which the movement of the wires within the core of the lead causes wear on the silicone insulation. Insulation abrasion increases the risk that the lead will malfunction, and if the action of the wires abrades completely through the outer silicone coating, an "externalized conductor" can result. Abrasion or an externalized conductor can be difficult to detect with non-invasive methods, and even if it is discovered, explanting and replacing a compromised lead presents its

own dangers to the patient. The Lead Plaintiff alleges that SJM had received reports of inside-out abrasion and externalized conductors as early as 2005, which prompted it to conduct an internal audit in 2008 that confirmed 246 cases of insulation breach in Riata leads.

The other flaw that had arisen with SJM's silicone-insulated leads in the field was electrical malfunction that was not caused by externalized conductors. This problem had been implicated in reports of the deaths of patients implanted with Riata and Riata ST leads that were submitted to SJM and the FDA's MAUDE database as early as 2006.

A. First Dear Doctor letter.

With these reports from the field in hand, SJM issued a "Dear Doctor" advisory letter on December 15, 2010, to provide physicians with "performance information regarding lead abrasion failures identified in the Riata silicone insulated defibrillation leads as compared to our newer lead models utilizing the Optim® insulation material . . . ." The letter related that abrasion of the silicone insulation had been observed in .47% of the 227,000 Riata and Riata ST leads SJM had sold over the preceding nine years. SJM explained that the insulation abrasion seen in those leads can be caused by either inside-out wear or by other factors, such as movement of the insulated lead against the metal of the implanted pacemaker or ICD, against a part of the patient's anatomy, or against another lead. SJM also represented that its "newer generations of defibrillation leads utilizing the Optim insulation material have demonstrated a reduction in lead abrasion-related observations by greater than 80% ($p < 0.0001$) at 44 months of follow-up as compared to our silicone leads." The letter went on to announce that, "[b]ased on the above data and demonstrated superior abrasion resistance of defibrillation leads utilizing Optim insulation,

[SJM] is completing the planned phase-out of all models of Riata and Riata ST silicone leads by December 31, 2010."

Following SJM's decision to discontinue sales of Riata and Riata ST, Dr. Ernest Lau, a heart device expert at Royal Victoria Hospital in Northern Ireland, conducted a study of these leads, and he presented the findings at the European Society of Cardiology Congress in August 2011. Dr. Lau reported that, upon screening a pool of patients implanted with Riata and Riata ST leads, 15% of them were found to have externalized conductors. Those findings were in sharp contrast to the data provided by SJM in its December 2010 Dear Doctor letter, in which the company stated that, of the .47% all-cause abrasion rate seen with Riata and Riata ST, approximately 10% of those reported abrasion events involved an externalized conductor.

B. Second Dear Doctor letter.

According to the Lead Plaintiff, in addition to being confronted with the results of Dr. Lau's study, SJM continued to receive reports of premature insulation abrasion and electrical malfunction in its silicone-insulated leads in the months after the issuance of its Dear Doctor letter. Then, on November 28, 2011, SJM issued another advisory letter "to provide updated estimates of failures associated with all cause insulation failure in our Riata® (8Fr) and Riata ST (7Fr) silicone endocardial defibrillation leads, with a specific emphasis on externalized conductors." In this letter, while referencing Dr. Lau's study and several other peer-reviewed publications, SJM upped the overall rate of all-cause insulation abrasion in the Riata family of silicone leads to .63% and indicated that approximately 15% of those abraded Riata leads exhibited an externalized conductor. SJM also stated that 99.9% of the 278,000 Durata and Riata

ST Optim leads then on the market had not exhibited abrasion of any kind, and that there had been no reports of externalized conductors in any Optim-insulated leads.

A few weeks later, in December of 2011, the FDA classified SJM's removal of the silicone-insulated Riata and Riata ST leads from the market a year prior as a Class I recall, indicating that the FDA considers those leads "to be in violation of the law it administers" and that "there is a reasonable probability that [their] use . . . will cause serious adverse health consequences or death." 21 C.F.R § 7.3(g), (m)(1).

By that time, SJM's silicone-insulated leads, thousands of which remained implanted in patients, were the subject of intense scrutiny, and concern was growing that SJM's Optim-insulated leads could be prone to the same problems. Dr. Robert Hauser, a Minneapolis Heart Institute cardiologist, was outspokenly critical of SJM's handling of the situation. In March of 2012, the online journal of the Heart Rhythm Society published a peer-reviewed article by Dr. Hauser and his colleagues, who had analyzed adverse event reports related to Riata and Riata ST leads from the FDA's MAUDE database. In contrast to the emphasis SJM had placed on externalized conductors in its Dear Doctor letter, Dr. Hauser concluded in his article that Riata and Riata ST leads "are prone to high-voltage failures that have resulted in death" which were not attributable to externalized conductors but rather "appeared to have been caused by insulation defects that resulted in short circuiting between high-voltage components."

C. Third Dear Doctor letter.

Shortly afterwards, on April 3, 2012, SJM issued a third Dear Doctor advisory letter to "proactively inform clinicians of the existence of visual observations of externalized conductors due to abrasion of the silicone insulation in [the silicone-insulated] QuickSite and QuickFlex

leads." In the letter, SJM indicated that the reported rate of externalized conductors in these pacing leads was .023%, though it acknowledged under-detection of the anomaly and estimated that a higher rate – 3-4% of the 101,000 QuickSite and QuickFlex leads then on the market – may be more accurate. SJM, while noting that it had received no reports of externalized conductors in its new generation of Optim-insulated QuickFlex µ and Quartet pacing leads, also announced that it would immediately discontinue the sale of QuickSite and QuickFlex leads.

VI. FDA attention in 2012-13.

Several months later, in August of 2012, the FDA ordered SJM to conduct post-market surveillance studies on the potential for premature insulation failure in its silicone-insulated leads – the recalled Riata and Riata ST and the withdrawn QuickSite and QuickFlex – as well as in its Optim-insulated Durata and Riata ST Optim leads.

Shortly thereafter, in September and October of 2012, the FDA conducted inspections of SJM's facilities in Sylmar, California and Arecibo, Puerto Rico, focusing on the company's production of the Durata. Both inspections resulted in the issuance of a Form 483. With the Arecibo Form 483, the FDA inspectors noted objectionable conditions related to the quality system in place at that facility, including inadequate procedures for product handling and complaint processing. The Sylmar Form 483, issued at the close of that inspection on October 17, 2012, included a number of observations of objectionable conditions in the manufacture of the Durata lead, such as inadequate design verification and testing, improper risk analysis and design validation, missing design history files, and insufficient MDR reporting.

In the months that followed, the FDA determined that the responses of SJM management to some of the items listed in the Form 483 for the Sylmar inspection were either inadequate or

unsubstantiated. As a result, in January of 2013, the FDA took the next step and issued a Warning Letter instructing SJM to rectify the problems and communicating its position that, until it did so, SJM's Durata and Riata ST leads "are adulterated within the meaning of [the Food, Drug, and Cosmetic Act] in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation . . . ."

Discussion

Against this backdrop, the Lead Plaintiff brings two counts of securities fraud under the Securities Exchange Act of 1934 ("SEA"). Count I is brought against both SJM and the five individual defendants under SEA § 10(b) and Rule 10b-5. Section 10(b) makes it "unlawful for any person . . . [t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of [the Securities and Exchange Commission's] rules and regulations . . . ." 15 U.S.C. § 78j(b). The SEC's Rule 10b-5, in turn, prohibits "mak[ing] any untrue statement of a material fact or . . . omit[ting] to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . ." 17 C.F.R. § 240.10b-5(b). The Supreme Court has inferred a private cause of action from the text and purpose of § 10(b) and Rule 10b-5; the elements are: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309, 1317 (2011) (internal quotation and citations omitted).

Count II of the ACC is brought against the five individual defendants only under the "control person" liability provision at SEA § 20(a). That section of the statute makes a "person who, directly or indirectly, controls any person liable under [§ 10(b) and Rule 10b-5] liable jointly and severally with and to the same extent as such controlled person . . . , unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a).

On their Motion to Dismiss, the Defendants argue that the Lead Plaintiff has not adequately pled the first two elements of its § 10(b)/Rule 10b-5 claim in Count I. Consequently, the Defendants argue, the "control person" liability claim asserted in Count II fails as well because it is predicated upon a primary violation of the securities laws, and the ACC should therefore be dismissed in whole.

The motion thus turns on the adequacy of the Lead Plaintiff's allegations in the ACC regarding (1) the Defendants' misrepresentations or omissions of material facts and (2) scienter. The pleading of these two elements is governed by the Private Securities Litigation Reform Act of 1995 ("PSLRA"), *see* 15 U.S.C. § 78u-4(b)(1)-(3), the requirements of which are "more rigorous than those under Rule 9(b) of the Federal Rules of Civil Procedure." *Lustgraaf v. Behrens*, 619 F.3d 867, 874 n.2 (8th Cir. 2010) (citation omitted). But as with any motion to dismiss for failure to state a claim on which relief can be granted, "courts must . . . accept all factual allegations in the complaint as true" and "consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

The Court will consider the Lead Plaintiff's pleading of the two elements in turn.

I. Misrepresentations or omissions of material facts.

The first element of a private securities fraud action under § 10(b) and Rule 10b-5 is that the defendant made an "untrue statement of a material fact" or "omit[ted] to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). *See Matrixx Initiatives*, 131 S.Ct. at 1317. To survive a motion to dismiss, the PSLRA requires that the complaint "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . state with particularity all facts on which the belief is formed." 15 U.S.C. § 78u-4(b)(1).

Thus, a properly-pled complaint not only includes the "who, what, when, where, and how" of the alleged misstatements, but also contains sufficient factual matter to "indicate[] why the alleged misstatements were false when made." *In re St. Jude Medical, Inc. Securities Litigation*, 836 F.Supp.2d 878, 887 (D.Minn. Dec. 23, 2011) (quoting *In re 2007 Novastar Financial, Inc. Sec. Litig.*, 579 F.3d 878, 882 (8th Cir. 2009) and *Lustgraaf*, 619 F.3d at 874).

Here, the Lead Plaintiff alleges in the ACC that the Defendants misrepresented or omitted material facts in a long series of statements they made in a variety of contexts throughout the proposed class period, which stretches from February 2010 to November 2012. The Defendants do not challenge the Lead Plaintiff's pleading of the "who, what, when, where, and how" of these statements. Rather, the Defendants argue that the Lead Plaintiff has not adequately alleged

the reasons why the statements were false or misleading as to material facts when they were made.

Accordingly, the Court will consider the alleged misstatements that are contested by the Defendants in light of the alleged facts, which will be divided three ways for the sake of analysis.

A. Regulatory compliance and quality controls.

First, the Lead Plaintiff alleges that "the Defendants made materially incomplete, false and misleading statements, and/or omitted material information, regarding the Company's quality controls and oversight which created the false impression to the investing public that [SJM] had the requisite internal procedures and controls in place to ensure that the Company was in compliance with applicable laws and regulations." ACC ¶ 183, ECF No. 48. The actual state of affairs, according to the ACC, was that SJM's quality controls over the design, production, and post-market monitoring of its leads were chronically deficient and were the subject of scrutiny and repeated criticism from the FDA.

In particular, the Lead Plaintiff emphasizes the objectionable conditions cited by the FDA in the four Form 483s SJM received after the inspections of its Arecibo facility in 2010 and 2012 and of its Sylmar facility in 2009 and 2012. SJM disclosed only the last of those publicly – and then in a controversial manner[1] – but all of them allegedly identified deficiencies in SJM's quality system at facilities where its defibrillation and pacing leads were designed, tested, and produced and where SJM was responsible for processing and investigating complaints and reports of adverse events from the field.

[1] SJM's disclosure of the Form 483 it received after the FDA's inspection of Sylmar in October 2012 is discussed in more detail in Section I.C.2 below.

In the face of the recurring objectionable conditions allegedly documented in these Form 483s, the Defendants argue that the ACC does not demonstrate that the FDA's critiques were anything more than isolated and perhaps inevitable incidents in the highly-regulated and constantly-evolving field of medical device manufacturing. However, in this posture, all reasonable inferences from the alleged facts are due to the Lead Plaintiff. In that light, the ACC does sufficiently allege a pattern of objectionable conditions and significant lapses in quality controls on the part of SJM's CRMD and IESD that began in the years prior to the class period and continued through it.

1. February 2010 investor call and October 2011 earnings call.

In light of this alleged pattern of deficient quality controls, the Lead Plaintiff alleges that two statements made by Defendants Fain and Rousseau during an investor conference call on February 5, 2010 touting SJM's focus as an organization on the quality and reliability of its products were actionably false or misleading. The ACC quotes Defendant Fain as saying that

> [o]ver the last few years we also have established ourselves as the industry leader for quality and reliability, with a proven track record of high quality product designs and performance. And what we are hearing back from our customers is that our ability to help them reduce risk for their patients really is becoming a key differentiator in the market place.

Id. ¶ 185. Similarly, Defendant Rousseau is quoted as stating that

> our focus on reliability is tireless. This is the single most important thing we look at when we design technology. We have strict design rules. We are always looking to improve the technology, that's the starting point, and I think the engineering team has come up with a best-in-class device here relative to all the things you want in an ICD.

Id. ¶ 186.

In addition, the Lead Plaintiff alleges that a statement made by Defendant Starks during an earnings call on October 19, 2011 created a materially misleading impression as to the reliability of SJM's leads. Defendant Starks is quoted as saying that SJM has

> the most robust post-market surveillance of lead reliability of anybody in the industry. You know, a lot of times people would talk about the limitations of passive reporting, and we always point out that we have the most robust active reporting, active follow-up of our device reliability including our ICD lead reliability.
>
> . . . So, if you look at all of the fine print in the product performance reports that come out in the CRM space, you'll see that we break out more data and that the input into our data are far more comprehensive and robust than is the case from other organizations. So we have a lot of confidence that we have a good handle on St. Jude Medical device reliability.

Id. ¶ 218.

The Lead Plaintiff alleges that all three of these statements are false or misleading as to material facts because the Defendants failed to disclose the persistent inadequacies in SJM's quality system that would undermine any claim it could make to being "the industry leader for quality and reliability" based on its "strict" design rules, "proven" track record, and "robust post-market surveillance."

However, these statements are transparently promotional and would not "have assumed actual significance in the deliberations of the reasonable shareholder." *In re K-tel*, 300 F.3d at 897 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). They are the sort of "vague, soft, puffing statements or obvious hyperbole" on which no reasonable investor would rely in making a decision about buying or selling SJM's stock. *Id.* (quoting *Parnes v. Gateway*, 122 F.3d 539, 547 (8th Cir. 1997)). While the Lead Plaintiff takes exception to the sentiments expressed by the Defendants, their boasting about SJM's "best-in-class device" and its "robust post-market surveillance" system is simply "not specific enough to perpetuate fraud on the market." *Id.* at 899.

These statements are therefore immaterial as a matter of law and, on that basis, are not actionable. *See id.* at 897 (directing that "if no reasonable investor could conclude public statements, taken together and in context, were misleading, then the issue [of materiality] is appropriately resolved as a matter of law") (quoting *Silver v. H&R Block Inc.*, 105 F.3d 394, 396 (8th Cir. 1997)).

2. SEC filings.

Next, the Lead Plaintiff alleges that SJM made actionably misleading statements and omissions of material facts regarding the company's commitment to regulatory compliance in a series of annual and quarterly reports it filed with the SEC between March 2010 and August 2012.[2] In those reports, which were certified by Defendants Starks and Heinmiller, SJM allegedly represented under the heading of "Regulatory Matters" that it was "regularly monitoring, assessing, and improving its internal compliance systems and procedures so that its activities will be consistent with applicable laws, regulations and requirements, including those of the FDA." ACC ¶ 189, ECF No. 48. SJM allegedly included this statement in all of the reports along with a discussion of FDA inspections of its (non-CRMD) manufacturing facilities in Minnetonka, Minnesota and Plano, Texas in 2008 and 2009 that had both resulted in the issuance of a Form 483s. However, according to the ACC, these reports made no mention of the Form 483s that SJM received following the FDA's inspection of its CRMD facilities in Sylmar in 2009 and at Arecibo in 2010 and 2012.

[2] The Form 10-K annual reports at issue were filed in March 2010, March 2011, and February 2012; the Form 10-Q quarterly reports were filed in May 2010, November 2010, May 2011, August 2011, November 2011, May 2012, and August 2012.

The Eighth Circuit has directly addressed a company's failure to disclose a Form 483 in this context, explaining that

> for purposes of pleading a securities fraud claim, the issuance of Form 483s may render a defendant's statement about its compliance with FDA regulations or cGMP false, or at least misleading, in some circumstances. The FDA's issuance of Form 483s may be material depending on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA. There is a substantial likelihood the presence of these factors would be viewed by a reasonable investor as significantly altering the total mix of information made available, irrespective of whether the Form 483 represents the FDA's final say on compliance issues.

Public Pension Fund Group v. KV Pharmaceutical Co., 679 F.3d 972, 982-83 (8th Cir. 2012). Therefore, at bottom, "[t]he issuance of a Form 483 represents a risk that the FDA may take corrective action against a company, and thus a company is obligated to assess the seriousness of the risk and disclose such information to potential investors if it also represents it is in compliance with FDA regulations and cGMP." *Id.* at 982.

Here, the Defendants argue that the failure to disclose the Sylmar and Arecibo Form 483s does not render the statements in its SEC filings actionably false or misleading because SJM did not represent that it was in compliance with FDA regulations and cGMP. In this respect, the Defendants assert that SJM made only aspirational and forward-looking statements of its commitment to "improv[ing]" its quality controls so that they "will be" FDA-compliant. The Defendants further argue that SJM's disclosure of the Minnetonka and Plano Form 483s necessarily dispelled any notion that it was in perfect compliance with FDA regulations.

This argument, however, relies on a parsing of the ACC that is not appropriate in this posture. The ACC does not allege that the statements of SJM's commitment to bringing its operations into regulatory compliance were made in a vacuum, but rather in conjunction with other statements disclosing FDA actions arising from the inspections of the Minnetonka and

Plano facilities. Together, those statements are susceptible to a reasonable inference by a reasonable investor that SJM had otherwise had no adverse interactions with the FDA over its compliance with cGMP – and in particular in its CRMD operations – which, according to the allegations in the ACC, was not the case. *See In re Medtronic Inc. Sec. Litig.*, 618 F.Supp.2d 1016, 1031 (D.Minn. March 10, 2009) (finding that a statement is actionably misleading if it "create[s] an impression of a state of affairs" that "materially differed from the one that actually existed"). Furthermore, the reports at issue were made over a period of time during which the ACC alleges that the safety and reliability of SJM's leads became the focus of ever-increasing scrutiny; in that context, the materiality of the FDA's recurring criticisms of SJM's quality system at its CRMD facilities is sufficiently alleged.

It is true, as the Defendants emphasize, that the securities laws "do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives*, 131 S.Ct. at 1321. *See also Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988) ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). By the same token, however, where the Defendants chose to speak on the company's interactions with the FDA, they had a duty not to make "inaccurate, incomplete or misleading disclosures." *In re K-tel*, 300 F.3d at 898 (internal quotation omitted). The ACC adequately alleges that the Defendants violated that duty in these SEC filings.

B. Safety and reliability of the older generation of silicone-insulated leads.

The second set of facts alleged in the ACC centers on the safety and reliability of SJM's older generation of silicone-insulated leads – the Riata and Riata ST defibrillation leads, and the QuickSite and QuickFlex pacing leads. With respect to the defibrillation leads, the Lead Plaintiff

alleges that SJM was aware throughout the class period of "electrical malfunctions . . . that were causing patient deaths and that would ultimately negatively affect [SJM's] future profitability . . . ." ACC ¶ 183, ECF No. 48. The ACC alleges that SJM received a steady stream of adverse event reports, beginning in 2006 and continuing through the class period, of the deaths of patients implanted with SJM leads; from those reports, Dr. Hauser and his colleagues concluded in the article published in *Heart Rhythm* in March 2012 that 20 deaths had "resulted directly from electrical malfunctions in the Riata and Riata ST leads . . . ." *Id.* ¶¶ 76-77.

With respect to the silicone-insulated pacing leads, the ACC alleges that SJM was also aware of "insulation issues with its QuickSite and QuickFlex CRT leads . . . ." *Id.* ¶ 183. Specifically, the ACC asserts that SJM knew that QuickSite and QuickFlex leads were experiencing the same premature abrasion problems in the field as the Riata and Riata ST leads, owing to their shared all-silicone insulation. *Id.* ¶¶ 95, 105.

1. December 2010 Dear Doctor letter and November 2011 conference call.

Against this backdrop, the ACC alleges that the Dear Doctor advisory letter SJM issued in December 2010 was actionably misleading because it omitted material facts about "the pervasive problems associated with the Riata and Riata ST leads, including, but not limited to, the numerous deaths related to electrical malfunctions in the leads, of which it was aware." *Id.* ¶ 202. In this Dear Doctor letter, SJM discussed the abrasion rate for the Riata family of silicone-insulated leads, explained the main causes of insulation abrasion, and represented that "[l]ead insulation abrasion can present with various clinical observations if the associated conductors become exposed and then come in contact with other leads or devices." The letter, however,

allegedly made no mention of the electrical malfunctions that had been reported in abraded Riata and Riata ST leads where the conductors had not become externalized.

For the same reason, the ACC also alleges that Defendant Heinmiller's statement at a health care conference in November of 2011 was actionably misleading. Consistent with the company's Dear Doctor advisories, he is alleged to have represented that "there was a 'very low level anomaly' in the Riata products that had been implanted, and that 'normal follow-up' and 'monitoring the system' was the recommending course of continuing treatment and management with respect to Riata." *Id.* ¶ 227.

The Defendants argue that these statements were not actionably false or misleading as to the safety and reliability of the Riata family of leads because the abrasion statistics and information on externalized conductors cited therein were accurate and, at the time they were made, SJM had no additional knowledge of electrical malfunctions to disclose. According to the Defendants, SJM was not aware of the problem of electrical malfunctions in the Riata family of leads until Dr. Hauser published his article in March of 2012 – and even then, it disagreed with his conclusions. Therefore, the Defendants contend, the Lead Plaintiff's allegations amount to pleading "fraud by hindsight," in that SJM cannot be faulted for omitting information in December of 2010 or November of 2011 that did not exist until March of 2012.

This argument is not persuasive. It is true that "[c]orporate officials need not be clairvoyant," *In re K-tel*, 300 F.3d at 891 (quoting *Novak v. Kasaks*, 216 F.3d 300, 309 (2nd Cir. 2000), and so "alleging that defendants made a particular statement at a given time . . . and then showing in hindsight that the statement is false" would be insufficient under the PSLRA. *In re Navarre Corp. Sec. Litig.*, 299 F.3d 735, 743 (8th Cir. 2002). Here, however, the ACC unambiguously alleges that the Defendants knew at the time that these statements were made that

Riata and Riata ST leads were prone to electrical malfunctions which were not caused by externalized conductors and that had resulted in patient deaths. According to the ACC, SJM had received those adverse event reports continuously since at least 2006 and understood their implications. Furthermore, the ACC includes a quotation from a New York Times article printed the day after Dr. Hauser's article was published, in which SJM's Chief Medical Officer is reported to have said that "[SJM] had not called more attention to the electrical malfunctions – in contrast to its warnings about the protruding wires – because the electrical failures were far more common." ACC ¶ 132, ECF No. 48. Here, those allegations are accepted as true, and they are sufficient to satisfy the Lead Plaintiff's pleading obligations with respect to the Dear Doctor letter and Defendant Heinmiller's statement at the health care conference. *See In re K-tel*, 300 F.3d at 891 ("Under the [PSLRA,] the complaint must allege 'facts or further particularities that, if true, demonstrate that the defendants had access to, or knowledge of, information contradicting their public statements when they were made.'") (quoting *In re Navarre*, 299 F.3d at 742).

The Defendants argue alternatively that SJM was not obliged to disclose the information it allegedly possessed about electrical malfunctions in Riata and Riata ST leads because the adverse event reports evincing the problem were publicly accessible in the FDA's MAUDE database. In support, the Defendants rely on *Sailors v. Northern States Power Co.* for the proposition that there is "no duty to disclose if investors have ready access to the information involved." 4 F.3d 610, 613 (8th Cir. 1993) (internal quotation omitted).

That case, however, is not amenable to the use to which the Defendants attempt to put it. There, the defendant utility company had applied to the state public utilities commission for a rate increase; when the application was denied, the company's stock dropped significantly and a private § 10(b)/Rule 10b-5 action soon followed. *Id.* at 611. In alleging fraud on the market, the

plaintiff conceded that the utility company had disclosed the application and the consequences that could come with its denial, but alleged that the company should also have publicly discussed its strategy in litigating the application and how it was faring at each step of the regulatory proceeding. *Id.* at 612. The Eighth Circuit rejected that contention, emphasizing the "vast amount of publicity concerning [the defendant's] rate proposal" in both "the mass media and specialized press" – indeed, the plaintiff itself alleged that it had relied on the media reports chronicling the regulatory proceeding – as well as the fact that the alleged omissions were "public information" contained in "public filings." *Id.* at 613. At bottom, the court determined that, "having alerted the market to the existence of regulatory proceedings," the defendant had no duty to "engage in a day-by-day, play-by-play announcement of the proceeding." *Id.* at 612, 614.

Here, the Defendants' argument elides the premise on which the Eighth Circuit drew its conclusion. The core of the ACC's allegations is that, with the Dear Doctor letter and Defendant Heinmiller's statement, SJM chose to speak on premature insulation abrasion in Riata and Riata ST leads but failed to alert the market to the existence of the electrical malfunctions that it knew were caused by that problem. That failure, the Lead Plaintiff asserts, rendered the picture of the risks associated with insulation abrasion that SJM allegedly painted in these statements materially incomplete and created the false impression that the silicone leads were safer and more reliable than they actually were.

The ultimate inquiry is whether these statements were misleading "in the light of the circumstances under which they were made." 17 C.F.R. § 240.10b-5(b). In the factual circumstances that the Lead Plaintiff has pled, the ACC adequately alleges that the Dear Doctor letter and Defendant Heinmiller's comments "omit[ted] material fact[s] necessary in order to

make the statements made . . . not misleading." *Id. Cf. Detroit General Retirement System v. Medtronic, Inc.*, 621 F.3d 800, 806-07 (8th Cir. 2010) (finding allegation that Dear Doctor letter was materially misleading insufficient under the PSLRA because plaintiff had not pled facts to show that omitted information was inconsistent with the letter and known to the defendant at time the letter was issued).

2. October 2011 earnings call.

Next, the Lead Plaintiff alleges that Defendants Starks made a statement during an earnings call in October of 2011 that was also actionably misleading as to the safety of the Riata family of leads. On that call, Defendant Starks was questioned regarding the study conducted by Dr. Lau that had shown a much higher incidence of externalized conductors in Riata leads than SJM had related in its December 2010 Dear Doctor letter. In response, he allegedly "downplayed Dr. Lau's study as 'a study by one center in Northern Ireland that documented partial failures of ICD lead insulation' and that 'used mostly eight French leads.'" ACC ¶ 216, ECF No. 48. According to the Lead Plaintiff, this statement was materially false or misleading because Defendant Starks failed to disclose the mounting cases of electrical malfunctions in Riata and Riata ST leads.

The Lead Plaintiff's pleading falls short here, however. Unlike in the Dear Doctor letter, Defendant Starks with this statement is not alleged to have made any representations as to the scope or consequences of all-cause abrasion problems in Riata leads. Instead, he answered a specific question about Dr. Lau's study with factual information that the ACC nowhere alleges to have been inaccurate or misleading. This statement did not create any impression as to the safety of SJM's leads and is therefore not actionable.

3. 2011 and 2012 Form 10-K annual reports.

The ACC also highlights a statement, included in the Form 10-K annual reports SJM filed with the SEC in March 2011 and February 2012, that "[i]n December 2007, we released the QuickFlex™ family of LV leads in the United States and Europe." *Id.* ¶¶ 203, 234. The Lead Plaintiff alleges that this statement was materially misleading because "Defendants failed to disclose internally-known abrasion issues with the QuickSite and QuickFlex leads, which were substantively similar in design to the Riata and Riata ST that were withdrawn from the market in December 2010." *Id.* ¶ 204(e).

This statement, however, is not actionable. Similar to Defendant Starks' statement discussed above, it conveys no information whatsoever about the safety or reliability of QuickSite and QuickFlex leads and makes no representations as to their performance in the field. Again in contrast to the December 2010 Dear Doctor letter, the statement creates no impression that could have conceivably misled a reasonable investor.

C. Design, testing, and reliability of the newer generation of Optim-insulated leads.

The third set of facts in the ACC revolves around alleged deficiencies in the design, testing, and performance of SJM's newer generation of leads, the Optim-insulated Riata ST Optim and Durata. In this respect, the Lead Plaintiff again emphasizes the FDA's inspections of the Sylmar and Arecibo manufacturing facilities in 2009, 2010, and 2012, pointing in particular to the objectionable conditions cited in the Form 483s and the January 2013 Warning Letter that pertained to the development and production of the company's Optim-insulated leads.

In addition, the ACC includes the allegations of a confidential witness ("CW1") who was employed by SJM during the class period as a Scientist and Senior Research and Development

Engineer. *Id.* ¶¶ 115-16. CW1 asserts that SJM manipulated the testing of Optim to "mask[] the relationship between failure rates and length of implantation" of the leads and to conceal that "Durata 'looks better than Riata' in the first few years after implant, but . . . 'after that it is probably no safer.'" *Id.* ¶ 117. CW1 also alleges that SJM "resisted" the results of internal testing that showed that Optim was "prone to wrinkle, which greatly increased risk of abrasion and other types of degradation," *id*. ¶ 120, and that the company categorized explanted leads that were returned to the company as showing no abrasion unless "it goes all the way through to breach," *id.* ¶ 121.

Finally, the ACC alleges, SJM was aware that Durata was prone to the same premature abrasion problems in the field that had arisen with the Riata family of leads; the company had allegedly confirmed as early as April 2011 from an adverse event report that "internal abrasion and/or inside-out abrasion was manifesting in Optim-insulated Durata leads . . . ." *Id.* ¶ 97.

1. Statements differentiating Optim-insulated leads from silicone-insulated leads.

On these alleged facts, the Lead Plaintiff alleges that the Defendants made a series of actionably false or misleading statements during the class period in an attempt to distance its newer generation of Optim-insulated leads from the problems that had arisen with its silicone-insulated leads. The Defendants challenge the pleading of a number of these statements.

The earliest of the statements occurred on the February 5, 2010 investor call that marks the start of the class period, when Defendant Fain allegedly claimed that "the Optim material has demonstrated a significant reduction in insulation abrasion failures even when compared to the low rates for silicone leads." *Id.* ¶ 185. Similarly, in the Form 10-K annual reports SJM filed

with the SEC in March of 2011 and February of 2012, the company allegedly stated that Optim "has demonstrated a statistically significant reduction in the incidence of insulation abrasion when compared to our previous silicone insulated leads." ACC ¶¶ 203, 234. Likewise, in the December 2010 Dear Doctor letter, SJM represented that its "newer generation of defibrillation leads utilizing the Optim insulation material have demonstrated a reduction in lead abrasion-related observations by greater than 80% ($p < 0.0001$) at 44 months of follow-up as compared to our silicone leads." *Id.* ¶ 201.

Furthermore, on an earnings call on October 19, 2011, Defendant Starks allegedly responded to a question about whether "Riata . . . could develop into a more significant issue for [SJM]" by touting Optim as "50 times more resistant to abrasion than silicone." *Id.* ¶ 214. Defendant Heinmiller is alleged to have repeat this figure at a conference on November 30, 2011, stating that "we found in our bench type studies [that Optim] was 50 times more abrasion resistant than he silicone coating that is on the Riata leads . . . ." *Id.* ¶ 225.

In addition, in the second Dear Doctor advisory letter SJM issued, in November of 2011, the company allegedly stated that "[t]here have been no reports of externalized conductors in Durata and Riata ST Optim leads and 99.9% are free from abrasion." ACC ¶ 223. On investor calls in December of 2011 and February of 2012, Defendant Fain allegedly emphasized that no externalized conductors had been reported in SJM's Optim-insulated defibrillation leads and that they had a "very low incidence of all-cause mechanical failures". ACC ¶¶ 228, 231. Finally, on an investor call on May 8, 2012, Defendant Heinmiller allegedly stated that "about 85% of the design features of [Durata] are different than Riata." ACC ¶ 248.

The Defendants argue that all of these statements are inadequately pled because the Lead Plaintiff does not deny that SJM had conducted bench tests that did show that Optim is 50 times

more resistant to abrasion than silicone, that there had been no reports of externalized conductors in Optim-insulated leads, or that the design of Durata differed from that of the Riata family of leads. Further, the Defendants contend that the Lead Plaintiff impermissibly relies on the FDA's criticisms of SJM's operations at the Sylmar facility that were noted in the October 2012 Form 483 to explain why all of the statements attesting to the strength and reliability of Optim made in the months and years before were misleading; as a result, the Defendants argue, the allegations amount to nothing more than pleading fraud by hindsight.

This reading, however, is not true to the ACC. The Lead Plaintiff does not dispute the existence of the data on which the Defendants based their statements; the ACC alleges instead that the data was not a "reliable basis [on which] to tout Optim products as superior [to Riata] or to attempt to quell investor fears over the safety and reliability of its leads." *Id.* ¶ 114. In this respect, the ACC repeatedly charges that the Defendants' use of the data to tout Optim's safety was misleading because the company's internal testing and its handling of adverse event reports were shaped to produce certain results while its verification and validation of the Durata's design were not done in accordance with accepted standards. All of this, the Lead Plaintiff asserts, rendered the information that the Defendants presented to the market about Optim's durability materially incomplete and unreliable.

In addition, the Defendants' fraud-by-hindsight argument again misses the mark. As discussed above, the ACC adequately alleges a pattern of deficiencies in the quality system at SJM's CRMD and IESD facilities that existed and was known to the company throughout the class period, the implications of which apply as fully to the company's manufacturing of Durata as they do to the production of its silicone-insulated leads. The Form 483s and the January 2013 Warning Letter documenting those deficiencies are relevant – regardless of whether they were

issued before, during, or after the class period – and may be used to "confirm what a defendant should have known during the class period." *KV Pharmaceutical*, 679 F.3d at 981 (citing *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 272 (3rd Cir. 2005) (internal quotation omitted)).

Drawing on *In re Medtronic*, the Defendants offer that "[o]ne way to decide whether a statement is misleading because of a material omission is to ask whether investors would have had a different impression of the state of affairs had the defendants said, 'but you should also know' the omitted fact." Defendants' Memorandum, ECF No. 65 at 37 (citing *In re Medtronic*, 618 F.Supp.2d at 1031). Even by the Defendants' chosen test, it is apparent that a reasonable investor's impression of the safety and durability of SJM's Optim-insulated leads could have been affected by the knowledge that the design and testing data on which the Defendants based their assurances were compromised in the ways alleged in the ACC. These statements are therefore actionable.

2. Statements regarding 2012 FDA inspection of Sylmar.

Finally, the ACC alleges that the Defendants made a series of actionably false or misleading statements regarding the FDA's inspection of SJM's Sylmar facility in 2012. In particular, the Lead Plaintiff alleges that, with a Form 8-K that SJM filed with the SEC on October 24, 2012, the company released a heavily-redacted copy of the Form 483 it had received from the FDA at the conclusion of the Sylmar inspection a week prior. *Id.* ¶ 263. That redacted version of the Form 483 allegedly concealed "all references to the Durata and Riata defibrillator leads" and was accompanied by a statement from the company that "[i]t is important to note that none of the observations identified a specific issue regarding the clinical or field performance of

any particular device." *Id.* ¶ 263. SJM allegedly repeated that statement in a Form 10-Q that it filed with the SEC two weeks later. *Id.* ¶ 264.

The Defendants argue that these statements are inadequately pled on two grounds. First, the Defendants contend that the redactions SJM made to the Form 483 were not misleading as to any material facts because the ACC itself demonstrates that the company had previously alerted investors that the FDA was conducting inspections of its facilities focused on its defibrillator leads – of which it produced only two series, the Riata and the Durata. As a result, the Defendants argue, "no investor who reviewed the redacted product names would have blithely assumed that the observations were *not* related to Durata." Defendants' Memorandum at 65, ECF No. 65.

This argument is not persuasive. Far from showing that SJM had disclosed that the FDA was investigating its defibrillation leads generally, the ACC actually alleges that Defendant Starks had stated a week before the release of the redacted Form 483 that the company's Dear Doctor advisory letters "involving our Riata and Riata ST silicone leads have drawn extensive attention from the FDA" and that the company "would not be surprised" if the then-ongoing Sylmar inspection resulted in the issuance of a Form 483 and a Warning Letter. ACC ¶ 258, ECF No. 48. A reasonable inference that could be drawn by a reasonable investor, then, is that the information SJM had redacted from the Form 483 pertained only to Riata, when in fact the inspection had, according to the ACC, focused on the production of Durata. Thus, the ACC adequately alleges that "there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Matrixx Initiatives*, 131 S.Ct. at 1318 (quoting *Basi*c, 485 U.S. at 231-22).

The Defendants' second argument is that SJM's statement that the FDA had not "identified a specific issue regarding the clinical or field performance of any particular device" in the Form 483 is not actionable because it was, in fact, true. This is also unavailing. Even if the statement was literally true in that the FDA's inspection allegedly focused on SJM's compliance with Quality System regulations in the design and production of Durata rather than on the performance of those leads in the field, that does not preclude it from being actionable under the securities laws. *See SEC v. Gabelli*, 653 F.3d 49, 57 (2nd Cir. 2011) ("The law is well-settled . . . that so-called 'half-truths' – literally true statements that create a materially misleading impression – will support claims for securities fraud."). Here, the Lead Plaintiff asserts that the statement was a misleading half-truth because it created the impression that the FDA had not paid any particular attention to any one particular device at Sylmar, when it had allegedly focused sharply on the Durata.

That is a reasonable inference that could be drawn from SJM's statement, and the ACC adequately alleges that that impression was materially misleading in an environment in which investors were keenly aware of the ongoing problems that had led to the discontinuation of the silicone-insulated leads and were finely attuned to any hint that the company's newer generation of Optim-insulated leads could share their flaws.

II. Scienter.

The second element of a private securities fraud action under SEA § 10(b) and Rule 10b-5 is that the defendant made the false or misleading statements of material facts with "scienter." In the Eighth Circuit, scienter refers to either severe recklessness or intentional wrongdoing, and it can be established with evidence of "highly unreasonable omissions or misrepresentations that

present a danger of misleading buyers or sellers which is either known to the defendant, or is so obvious that the defendant must have been aware of it." *In re Ceridian Securities Litigation*, 542 F.3d 240, 244 (8th Cir. 2008) (internal quotation omitted). *See also Matrixx Initiatives*, 113 S.Ct. at 1323-24 (noting that Supreme Court has "not decided whether recklessness suffices to fulfill the scienter requirement," and assuming without deciding that "deliberate recklessness" suffices).

To survive a motion to dismiss, the PSLRA requires that the complaint, "with respect to each [allegedly false or misleading statement], state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). On a motion to dismiss, "[t]he inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 322-23. Furthermore,

> [t]o determine whether the plaintiff has alleged facts that give rise to the requisite "strong inference" of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the "smoking-gun" genre, or even the "most plausible of competing inferences. . . . Yet the inference of scienter must be more than merely "reasonable" or "permissible" – it must be cogent and compelling, thus strong in light of other explanations.

Id. at 324.

Therefore, a "complaint will survive [a motion to dismiss] only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

A. Motive and opportunity.

In one attempt to plead facts that would give rise to the requisite inference of scienter, the Lead Plaintiff alleges that Defendant Starks "was motivated to artificially inflate [SJM's] stock price during the Class Period in order to benefit his own personal financial situation with the proceeds from insider stock sales." ACC ¶ 284, ECF No. 48. The ACC alleges that these stock sales took place on October 31 and November 1, 2012, in the period after SJM released the redacted Sylmar Form 483 but before the company's efforts to conceal the FDA's focus on Durata came to light later in November. *Id.*

These allegations, however, do not give rise to a strong inference that Defendant Starks' alleged misstatements of material facts regarding SJM's leads were motivated by his desire to profit personally by selling his stock at an inflated price. Though it would appear from the allegations that Defendant Starks did profit very handsomely from the stock sales – and that he may not have fared as well if the sales taken place just a short time later – the ACC contains no indication that these transactions were out of the ordinary for him, whether in terms of their timing or the number of shares. Without this information, a strong inference of scienter is not warranted. *In re K-tel*, 300 F.3d at 896 (finding no inference of scienter could be drawn from insider stock sales where the plaintiffs "failed to allege the prior history of sales for the defendants or even the number of shares held by each").

B. Knowledge.

Nevertheless, the ACC's allegations of insider trading by Defendant Starks on a "motive and opportunity" theory of scienter are far from the only facts in the ACC that would give rise to a strong inference that the Defendants acted with the requisite state of mind. Indeed, the major

thrust of the ACC is that the "defendants made statements when they knew or had access to information suggesting these public statements to be materially inaccurate." *In re Navarre*, 299 F.3d at 746. The Eighth Circuit has characterized this as a "'classic' fact pattern giving rise to a strong inference of scienter . . ." *Id.*

Indeed, the Lead Plaintiff alleges throughout the ACC – and in detail – that the Defendants made statements of material facts about SJM's regulatory compliance, quality controls, and the safety and reliability of both generations of its leads while they were in possession of information that contradicted or undermined those representations. These allegations are discussed above, and they do not require further treatment here other than to affirm that the alleged facts do give rise to a cogent, compelling, and strong inference of scienter.

In an attempt to stave off this conclusion, the Defendants isolate the ACC's factual allegations from one another and articulate a plausible, innocent explanation for each of them. The question here, however, "is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter . . ." *Tellabs*, 551 U.S. at 324. Even though the Defendants offer plausible, nonculpable inferences from the alleged facts that are undoubtedly cogent and compelling, this is a motion to dismiss, and the inference of scienter need not be irrefutable to be adequately pled.

In short, the Lead Plaintiff's pleading gives rise to an inference that the Defendants made the allegedly false or misleading statements of material facts with scienter that is equally as cogent and compelling as any of the opposing inferences. In this posture and with respect to this element of the claim, that is all the ACC is required to do.

Conclusion

For the reasons and in the manner discussed above, the Court grants in part and denies in part the Defendants' Motion to Dismiss.

Based on the files, records, and proceedings herein, and for the reasons discussed above, IT IS ORDERED THAT:

1. Defendant's Motion to Dismiss the Amended Consolidated Complaint [ECF No. 63] is GRANTED IN PART and DENIED IN PART consistent with the memorandum above.

Dated: March 10, 2014

s/Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge